

REMARKS/ARGUMENTS

Claims 48 and 50-57 are pending and were examined. The claims have been amended, canceled, and new claims added as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

All examined claims were rejected as being anticipated by Evard '898. For convenience, references to Evard will be made with respect to the corresponding granted Evard patent U.S. Patent No. 6,616,675.

In general, Evard describes a "connecting apparatus" having deployable "engagement members" at either side of a cylindrical "connecting portion." In some instances, it is taught that the connecting apparatus "may be initially deployed in a radially compact state such that it may be advanced transluminally through the body to a desired implantation site, and is subsequently transitionable to a radially expanded configuration wherein the first engagement member will engage the first anatomical structure and the second engagement member will engage the second anatomical structure." Col. 2, lines 19-27. Exactly which portions of the apparatus are constrained and expanded together or separately varies within the specific embodiments disclosed in Evard. Moreover, very few teachings are provided on how the connecting apparatus may be deployed through adjacent tissue layers to form an anastomotic connection, as set forth in claim 48 herein.

Delivery of the connector apparatus is described in Cols. 20-22 of the '675 text. With reference to Figs. 14a – 14e, a variety of delivery catheters are illustrated and described, but in very little detail. A particular rivet delivery apparatus is illustrated in Figs. 15a and 15a'.

Of particular interest to the claims of the present application, none of the delivery catheters of Figs. 14a-14e illustrate how the engagement members of the connector apparatus deploy. Fig. 14a shows a simple tubular stent 10 expanding without any engagement structures. Similarly, the balloon delivery catheter of Fig. 14b shows balloon expansion of a simple stent without engagement structures. Fig. 14c illustrates a connector apparatus which may or may not have engagement structures (the stent is only partially deployed in the figure and may or may not have anchors) although none are described in the specification in Col. 21. Similarly, Fig. 14d

illustrates an alternative catheter for releasing a self-expanding apparatus 10, again without illustration of any engagement structures. Finally, Fig. 14e shows an alternative connector apparatus 10 having screw threads on its exterior.

Claim 48, the only pending independent claim herein, has been amended to set forth a particular aspect of the delivery method of the present invention, best illustrated with respect to Fig. 19 and described in paragraphs [0089] and [0090] of the published application. In particular, claim 48 has been amended to specify that a hollow cylindrical central member penetrated through proximal and distal tissue layers. A distal anchor on the central member of the assembly is then deployed to engage tissue on a distal side of the distal tissue layer, and a proximal tension is applied to the apparatus. The proximal tension continues to be applied while the proximal anchor is deployed from the central member on a proximal side of the proximal tissue layer, thus holding the assembly in place as the assembly expands within the adjacent tissue layers. No such deployment technique is remotely described in Evard.

The Examiner argues that Evard discloses a method of anchoring tissue comprising “positioning an apparatus . . . to a wall of a luminal structure; manually advancing an assembly member 10 comprising a central member 38a, 84, 94 through a tissue penetration; deploying first and second anchors from the central member engaging the tissue on the distal and proximal side 20, 92, wherein the radius of the central member expands . . . to provide a lumen . . . through the tissue. The deploying of the first and second anchor comprises self-expansion . . . The anchor is comprised of mesh . . .”

Without conceding that such description is complete or accurate, Applicants note that Evard does not disclose the additional limitations of claim 48 as now set forth. In particular, Evard fails to disclose applying a tension to the apparatus which is deploying the central member and anchors after the first anchor has been deployed and while the second anchor is being deployed and the central member is being radially expanded. Indeed, nothing in the specific teachings of Evard in Figs. 14a-e and 15a-15a' remotely teach that tension can be applied to the

delivery catheter at any point during the delivery protocols or even that the illustrated stent (central member) has anchors of any sort..

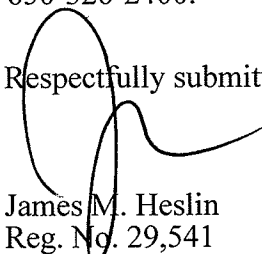
For these reasons, Applicants believe that independent claim 48, as amended, clearly distinguishes the teachings of Evard. Moreover, Applicants believe that all claims dependent on claim 48 are also allowable over Evard. Thus, it is believed that the present application is now in condition for allowance and requested that the application be passed to issue at an early date.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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